Service Area Office, East
Department of Veterans Affairs
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212

LIMITED SOURCES JUSTIFICATION
ORDER >$150,000
FAR PART 8.405-6

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide *original manufacturer's* name for material or contractor's name for service.

Manufacturer/Contractor: Beckman Coulter Inc.
Manufacturer/Contractor POC & phone number: Mark S. Watanabe 714-961-4288
Mfgr/Contractor Address: Beckman Coulter, Inc., Diagnostic Systems Group, 250 S. Kraemer Blvd., P.O. Box 8000, Brea, CA 92822-8000

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY: Department of Veterans Affairs – NCO 2
VAWNYHCS – Batavia VA facility
222 Richmond Ave Bldg 3 Rm 103
Batavia, NY 14020
VISN: 02

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:
The following justification is for the acquisition of a clinical microbiology cost per reportable result (CPRR) requirement. This requirement will provide the panels, instrumentation, and supplies necessary to perform bacteria identifications and antibiotic susceptibility testing. These tests are required in order to properly assess and treat patient infections.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:
The required clinical microbiology CPRR requirement is on FSS contract # V797P-7090A, which currently expires April 14, 2016. However, it should be noted that this FSS contract is in the negotiation process for the exercise of an option to extend the FSS contract through April 14, 2017. Additionally, Beckman Coulter is currently competing for a new FSS contract to include this MicroScan product line. This requirement is for a clinical microbiology CPRR for the use of a fully automated laboratory system, reagents and controls for the following tests: Gram Positive Identifications (ID's), Gram Negative ID's, and Antimicrobial Susceptibility Tests (AST). This system must have the ability to be manually read, must allow for "Combo" Panels (allowing bacterial identifications and susceptibilities to be performed at the same time), and provide a "true" MIC as opposed to the estimated MIC amongst other requirements. Further, one analyzer is needed at each of the following sites: VAWNYHCS Buffalo Site (Walkaway Plus), Syracuse VAMC (Walkaway Plus) and Albany-Stratton VAMC (Autoscan-4). This requirement is anticipated to be a Blanket Purchase Agreement against the FSS contract. The total estimated value of the BPA over five years is $413,820.00.

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(b) **ESTIMATED DOLLAR VALUE:** Base Year - $82,764.00 Life of BPA - $413,820.00

(c) **REQUIRED DELIVERY DATE:** 10/1/15 and negotiated dates thereafter during life of BPA

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.
Beckman Coulter is the only available source for the proprietary Microscan CPRR test kits required to perform highly specialized laboratory testing. The results obtained with this instrument are timely, sensitive, and specific. This requirement is for a clinical microbiology CPRR for the use of a fully automated laboratory system, reagents and controls for the following tests: Gram Positive Identifications (ID's), Gram Negative ID's, and Antimicrobial Susceptibility Tests (AST). This Microscan system provided by Beckman Coulter has the ability to be manually read, allows for "Combo" Panels (allowing bacterial identifications and susceptibilities to be performed at the same time), and provides a "true" MIC as opposed to an estimated MIC, which meets the VISN 2 laboratory requirements. The competition does not provide all of these features and notably provides an estimated MIC rather than a "true" MIC. Ultimately, the information provided by this analyzer is essential in the identification and proper treatment of patient infections. Further, the Microscan CPRR system is the only known system that meets these specific requirements.

☐ A patent, copyright or proprietary data limits competition. The proprietary data is:

☐ These are "direct replacements" parts/components for existing equipment.

☐ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

This clinical microbiology CPRR test is available on FSS contract (V797P-7090A). In the past, the laboratories in VISN 2 utilized the same testing system under a different FSS contract with Siemens Healthcare Diagnostics. Siemens Healthcare Diagnostics recently sold this product line to Beckman Coulter. Originally, the VISN 2 laboratories brought this test in house to save significant funds for the Dept. of Veterans Affairs. Send out services take more time to complete due to the transfer of specimens from one site to another and there is an associated delay in receiving/processing the results. Further, send out tests are more costly than completing these tests in house. Therefore, the laboratories in VISN 2 are seeking to keep this test in house. Moreover, Beckman Coulter has a strong history of positive past performance. There are currently no terminations listed in the FAPIIS database and no recorded instances of defective pricing. Additionally, Beckman Coulter's delivery system is highly efficient and therefore is able to provide the supplies for this CPRR test quickly. Finally, when negotiated, the Contracting Officer for the FSS contract sought the best value for these tests. In addition to this, the Contracting Officer for this requirement will seek additional discounts if possible.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

Extensive market research was conducted for this procurement. I contacted each of the companies listed on the FSS schedule whom provide clinical microbiology CPRR services. During this contact, I requested information about each of their testing systems. Specifically, I requested the following information: the system's ability to perform manual readings (when needed), whether the system generates a true (not extrapolated) MIC, whether the system flags unusual results, information regarding the data management capability of the system, whether the system has the ability to perform MIC testing of fastidious organisms, and whether the system can utilize "Combo" Panels (allowing bacterial identifications and susceptibilities to be performed at the same time). Ultimately, the results of these conversations showed that there has been no significant change in the operation of these varying clinical microbiology CPRR systems since the previous BPA evaluation and award. There is only one system that provides the ability to be manually read, allows for "Combo" Panels (allowing bacterial identifications and susceptibilities to be performed at the same time), and provides a "true" MIC. This system is the Microscan system available through Beckman Coulter.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

Previously, there was a Blanket Purchase Agreement (BPA) for this requirement through Siemens Healthcare Diagnostics, Inc., which was awarded on October 1, 2013 (VA528-14-A-0054). This BPA was for the Microscan clinical microbiology CPRR system. At the time of award of this BPA, a thorough evaluation of all of the available clinical microbiology CPRR services was completed. There have been no new clinical microbiology CPRR products added to these FSS contracts since this original evaluation. The results of this evaluation showed that only one clinical microbiology CPRR service met the needs of the laboratories in VISN 2; this testing system is/was Microscan. The needs of the VISN 2 laboratories have not changed; the same evaluation factors would be relevant to this procurement. Moreover, despite having unused options remaining, this original BPA is no longer valid as of September 30, 2015. This existing BPA is no longer valid because the Microscan CPRR product line is being removed from the underlying Siemens Healthcare Diagnostics FSS contract due to the sale of this product line to Beckman

Coulter, Inc. during FY15. Ultimately, Beckman Coulter has added the Microscan CPRR test to its FSS contract via Mod P00048.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:
There are no known actions that can be taken to overcome the barriers that led to this restricted consideration.

(9) REQUIREMENTS CERTIFICATION: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

SIGNATURE DATE

Laboratory Supervisor	Lab Service-113
NAME	TITLE	SERVICE LINE/SECTION

Syracuse VAMC
FACILITY

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP:

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

CONTRACTING OFFICER'S SIGNATURE DATE

NAME AND TITLE

NCO 2
FACILITY

b. Director of Contracting/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

DATE

NCO 2 Division Chief
See File for copy of the corresponding Delegation Memo